## REMARKS

### *Status of the Claims*

Claims 1-38 are pending.

Claims 1-2, 4-7, 9-14, 15-20, 22, 24-27, 29-32, 34, and 36-38 were rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Number 5,832,449 to Cunningham (herinafter "Cunningham).

Claims 3, 23, 28 and 35 were rejected under 35 USC 103(a) as being unpatentable over Cunningham as applied to claims 2, 22, 27, 34 respectively, and further in view of US Patent Number 5,666,490 to Gillings ("Gillings").

Claims 8, 21 and 33 were rejected under 35 USC 103(a) as being unpatentable over Cunningham, as applied to claims 1, 15, 27 respectively and further in view of US Patent Number 6,564,121 to Wallace ("Wallace").

Applicant traverses the rejections and requests reconsideration.

**Claims 1, 15, 22, 25, 27, 34 and 37 have been amended** to more explicitly claim the ability to integrate patient data with drug sample usage data in order to obtain data on the pre-identified patients who are prescribed the drug samples.

No new matter is added by way of these claim amendments.

***Argument***

Applicant submits that this Reply and Amendment places this application in condition for allowance by amending claims in manners that are believed to render all pending claims allowable over the cited art of Cunningham, Gillings and Wallace.

The claim amendments presented herein more explicitly claim the ability to integrate patient data with drug sample usage data in order to obtain data on the patients that are using the drug samples. The claims as amended herein incorporate the feature of adjudicating a health plan claim that is directed to, or based on, token usage by a pre-identified patient, that patient having been uniquely identified, or named, by a prescriber who has prescibed the drug to the pre-identified patient.

Support for this amended claim feature is found in at least **Figure 2b**, and paragraphs [0042], [0045], [0046] and [0058]. Patient Name **48** comprises patient pre-identification data that is originated on a token for a specifically named, prescribed patient by the prescriber **46**. Pre-identification is done at the time of the prescription by the prescriber 46, so that the token can be used by that pre-identified patient for the benefit representative thereof, a drug sample.

**Cunningham does not disclose a pre-identifed patient**

The Office Action at page 7 cautions that, with reference to the terminology "pre-identified" patient: *"Furthermore, even if these claims were amended to include these above mentioned terms, the Cunningham reference teaches this very feature, as noted above in the rejection of the claims (Cunningham: Figures 7A- 7B; Col. 9, Ln. 13- Col.10, Ln. 50)."*

Applicant respectfully disagrees, and submits that Cunningham does not teach the feature of a pre-identified patient, in contrast to the amended claims herein.

Nowhere in Cunningham *Col. 9, Ln. 13- Col.10, Ln. 50* is there disclosed or discussed a specifically identified patient being provided with the product trial media of Cunningham. For instance, the first section of that Cunningham citation, Col.9 Ln. 13 - Col. 10 Ln. 21, describes the process for a prescriber to activate the product trial media, but nowhere therein is mention of a specifically identified or prescribed patient.

Next, the paragraph starting at Col. 10 Ln. 22 refers to a participating patient, but this is in a generic sense of a participating patient:

> To dispense the pharmaceutical trial product represented by the activated product trial media, the prescriber signs the product trial media and delivers the same to a participating patient. The patient in turn presents the activated product trial media to a participating pharmacy for the purpose of filling the trial product prescription of the prescriber.

At least up to this point, there is no identification of a specific patient. In fact, such is not necessary to, or inherent in Cunningham, because Cunningham stresses a subsequent validation process whereby the product trial media is authenticated by the pharmacy, before the drug sample is provided (Col. 10):

> However, before the pharmacy can fill the prescriptive trial product of any presented product trial media **18**, the product trial media must be subjected to a "validation" procedure. The "validation" procedure is basically illustrated in FIGS. **7A–7B**. Essentially, this validation procedure establishes that the presented product trial media **18** is authentic, still within an acceptable date range, has been activated by a prescriber, and has not previously been validated. Once validation is established for any presented product trial media, then the participating pharmacy can issue the prescriptive trial pharmaceutical product to the patient.

That validation process is further described later in Col. 10, and continued in Col. 11 :

trial media. But briefly, the validation step entails the participating pharmacy establishing authorization. This can be carried out in a variety of ways. However, in the process contemplated herein, the participating pharmacy would communicatively connect its authorization media **20** with the pharmacy terminal and after establishing a valid authorization media the participating pharmacy would enter its personal identification code. Thereafter, the terminal prompts the pharmacy to read the presented product trial media **18** into the terminal. As an individual product trial



media is read into the pharmacist's terminal, the terminal first checks for complete authenticity of the presented product trial media **18**. Like with the prescriber, the identification of the media is checked, the date range of the media is checked and the terminal seeks a valid answer from the check digit/analog code fields. If authenticity is not established, it follows that the participating pharmacy cannot dispense corresponding pharmaceutical product. However, if authenticity is established then the pharmacies' terminal dials the central computing station and data and information from the pharmacies' authorization media and personal identification is uploaded to the database of the central computing station **12**. The central computing station

Again, nowhere is there mentioned specific identification of a patient as being relevant to, or being a necessary part of, the validation or authentication process.

Continuing at Ln. 19 of Col. 11:

product trial media **18**. In addition, both the pharmacy and the patient sign the now validated product trial media **18**. Once validation is established the pharmacy then dispenses pharmaceutical trial product authorized by that valid product trial media and permanently stores the validated media. At the same time, the central computing station **12** records the full validation data within its database by showing that a particular product trial media **18** has been validated, the date of such validation, and the identity of the pharmacy validating the same.

Note that the patient signing the validated product trial media, after authentication by the pharmacy, is the first mention or occurrence of a specific identification of the patient. The patient's identity is not a part of the authentication process for the product trial media of Cunningham.

Further with regard to Figures 7A- 7B cited by the Examiner, a review of those figures show not even a single reference to the term "patient", much less any reference to a "pre-identified patient". None of the data referred to in the steps of Figures 7A -7B refer to patient data. The "Personal Identification Code" disclosed in each of those figures 7A and 7B pertain to the prescriber and the pharmacy respectively, not of a specific patient.

Further reinforcing Applicant's interpretation above, at Cols. 11 and 12, the Cunningham method of tracking and managing the dispensing of pharmaceutical trial products is summarized thus:

> In summary, the present method of tracking and managing the dispensing of pharmaceutical trial products centers around the utilization of a group of authorized prescribers and pharmacies and a centralized computing station that is specifically linked to the participating prescribers and pharmacies. Product trial media capable of being exchanged at a pharmacy for pharmaceutical trial product is delivered in an unactivated state to participating prescribers. After establishing authorization, the prescriber through a remote terminal and the central computing station "activates" certain product trial media. Once activated, the product trial media is capable of being prescribed or exchanged for a pharmaceutical trial product at a participating pharmacy site. The activated pharmaceutical trial media **18** is then delivered to a patient and the patient in turn presents the same to a
>
> **12**
>
> participating pharmacy. The pharmacy must establish authorization to participate in the system and thereafter the presented activated product trial media is authenticated by the central computing station and is deemed valid. Next, the pharmacy dispenses the pharmaceutical trial product identified by that media. Thereafter, an audit and accounting function is performed based on the database associated with the central computing station. Accordingly, participating pharmacies can be compensated for the actual dispensed pharmaceutical product and for dispensing services performed.

Yet again, and consistent with Applicant's characterization and assertions above, nowhere in this summary does Cunningham require or disclose a specifically identified patient. Once the product trial media of Cunningham is authenticated by the

pharmacy, it is deemed valid and the pharmacy dispenses the drug identified by that product trial media.

Therefore the section of Cunningham cited by the Office Action cannot reasonably be interpreted to comprise a token being provided by the prescriber to a pre-identified patient for obtaining the pharmaceutical drug sample from the drug dispenser. A generic bearer of the product trial media of Cunningham appears to be entitled to the drug sample in exchange only when authentication of the product trial media at the pharmacy is successful.

**The Product Trial Media of Cunningham is not a Token**

The Merriam-Webster dictionary defines a token as "something given or shown as a guarantee (as of authority, right, or identity)."

Technically, but importantly, the product trial media of Cunningham is NOT a token provided by the prescriber to a pre-identified patient for obtaining the pharmaceutical drug sample from the drug dispenser, since at least until this point in time, it not something given as a guarantee of a right to a drug sample.

In Cunningham, only after authentication of the product trial media is successfully completed at the pharmacy is a right to a drug sample created. The pharmacy must successfully establish authenticity before the bearer has any right to a drug sample. No right to a drug sample exists at the time a prescriber provides the activated product trial media to a patient, and therefore no token is generated at this point. In fact, even when the patient renders the product trial media to the

pharmacy, and before authentication and determination of validity, it still cannot be considered a token since the right to a drug sample still has not yet been created.

In Applicant's instant case, the right to a drug sample, a "token" according to the strict meaning of the word, is created and exists once the prescriber identifies the specific patent on the card, and signs the card. No further validation is necessary, nor required, to perfect a right to a drug sample, unlike Cunningham. Cunningham therefore cannot be strictly interpreted to disclose a token provided by the prescriber to a pre-identified patient for obtaining the pharmaceutical drug sample from the drug dispenser, since at least until this point in time, a right to a drug sample does not exist.

Applicant submits that the above argument is not intended to be merely a semantics-based, "hair-splitting" argument, and respectfully requests the Examiner's full consideration on this point. Applicant is entitled to the benefit of carefully chosen terms in Applicant's disclosure, in this case the "token", being interpreted, however strictly, according to the actual meaning of that word.

None of the cited references of Cunningham, Gillings and Wallace, either alone, or in combination, discloses the Applicant's invention as presently claimed in claims 1-38, especially with regard to use of a token, representative of benefits such as drug samples, by a specific, pre-identified patient.

## *Conclusion*

Applicant respectfully submits that since the Examiner's cited references neither alone, nor in combination, disclose the Applicant's invention as presently claimed, for at least the reasons set out above, the application in its present form is in condition for allowance. Action toward that goal is respectfully requested.

The Examiner is kindly invited to contact applicant's agent Henry Ohab at 416.862.3593 if it would be of assistance in resolving any issues in this application.

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Respectfully submitted,

/Henry Ohab/

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